K013614

FEB 01 2002

510(k) Summary

Submitted by: ArmKel LLC
469 North Harrison Street
Princeton, NJ 08543

Contact Person: Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
(609) 655-6308

Date Prepared: November 1, 2001

Proprietary Name: TROJAN® CRYSTAL CLEAR Liquid

Common Name: Personal Lubricant

Classification Name: Patient Lubricant [21 CFR §880.6375]

Predicate Device: H•R® Lubricating Jelly
[Pre-1976 Amendments Device]
TROJAN® *FOR WOMEN* Personal Lubricant
[#K890863]

Description of Device: The TROJAN® CRYSTAL CLEAR Liquid personal lubricant is a water-soluble, greaseless, unscented, clear, colorless liquid, 2.1 oz of which is packaged in a clear plastic bottle.

Intended Use of the Device: A patient lubricant is a device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. The TROJAN® CRYSTAL CLEAR Liquid personal lubricant is principally intended to provide supplemental vaginal lubrication during sexual intercourse, and it may be used with condoms.

Technological Characteristics: There are no exceptional technological characteristics associated with TROJAN® CRYSTAL CLEAR Liquid. Although a proprietary formulation, the basic formulation of TROJAN® CRYSTAL CLEAR Liquid follows that of conventional water–soluble lubricant bases. [*e.g.*, *Remington's* Pharmaceutical Sciences, ed. XIV, 1970, Mack Publishing Co., Easton, PA., Chp 85.] Both the TROJAN® CRYSTAL CLEAR Liquid and the predicate lubricant devices follow conventional formulation concepts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FEB 24 2014

ARMKEL, LLC
% Mr. Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
469 North Harrison Street
PRINCETON NJ 08543

Re: K013614
Trade/Device Name: TROJAN® Crystal Clear Liquid Personal Lubricant
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated (Date on orig SE ltr): November 1, 2001
Received (Date on orig SE ltr): November 5, 2001

Dear Mr. Kolakowsky:

This letter corrects our substantially equivalent letter of February 1, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K013614

Device Name: TROJAN® CRYSTAL CLEAR Liquid Personal Lubricant

Indications for Use: The TROJAN® CRYSTAL CLEAR Liquid is principally designed to help enhance the sexual experience by providing supplemental vaginal lubrication during sexual intercourse. The TROJAN® CRYSTAL CLEAR Liquid may be used with condoms. The TROJAN® CRYSTAL CLEAR Liquid patient lubricant is a device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use X
(Per 21 CFR §8001.109)

David A. Ayers

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013614